

REMARKS/ARGUMENTS

Applicants have carefully reviewed the Office Action mailed on February 6, 2008. Applicants respectfully traverse all objections, rejections, and assertions made by the Examiner. With this amendment, claims 1, 14, and 27 are amended. Support for the amendments is found in the specification, claims, and drawings as originally filed. No new matter has been added. Claims 1-32 remain pending.

Claim Rejections under 35 U.S.C §103

Claims 1-4, 6-12, 14-18, and 23-32 were rejected under 35 U.S.C. §103(a) as being unpatentable over Cornwall et al. (U.S. Patent No. 6,485,518) in view of Davison (U.S. Patent No. 6,530,926). This rejection is respectfully traversed. Independent claims 1 and 14, as amended, recites in part, "after said inserting step, inclining said access device from a plane that is generally perpendicular to the spine of the patient"; emphasis added. Independent claim 27, as amended, recites in part:

inserting into said patient an access device having a medial side to a surgical location adjacent the spine, the access device having a first cross-sectional area at a distal portion thereof during insertion, wherein after inserting said access device, a plane extending posteriorly and including a longitudinal axis of the spine intersects said access device;

actuating said access device such that said distal portion has an enlarged cross-sectional area, wherein during said actuating said medial side of the access device moves toward the spinous process;

MPEP 2143.03 states, "[t]o establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)." Neither Cornwall et al. nor Davison appear to teach or suggest such specific method steps.

The Examiner asserts that the "substantially perpendicular plane of the spine, denoted by the dotted line in Fig. 1 of Cornwall et al. must be crossed by the minimally-invasive cannula to complete the procedure for both screws. Thus, Davis [sic] teaches the step, inherently, of the device moves from a plane generally perpendicular to the spine of the patient." Applicants respectfully disagree. Applicants note that claims 1 and 14 recite the method step of inclining the access device from a plane that is generally perpendicular to the spine of the patient. The Examiner appears to be interpreting the language of the claim to

mean the access device merely crosses a plane perpendicular to the spine. This interpretation is incorrect and inconsistent with the teachings in the specification. Cornwall does not appear to teach the active step of inclining an access device, as recited in independent claims 1 and 14.

Further, if the Examiner is asserting that Davison inherently teaches the step of inclining an access device from a plane generally perpendicular to the spine of the patient, there is no teaching or suggestion in Davison for such an interpretation. MPEP 2112 IV. states that inherency requires a feature to be necessarily present:

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is **necessarily present** in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)...

"In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).

(Emphasis added). Applicants submit that the claimed method steps, in particular the step of inclining the access device from a plane that is generally perpendicular to the spine of the patient, are not necessarily present in Davison. Additionally, there is no motivation for one of ordinary skill in the art to modify Cornwall and/or Davison to achieve the specific claimed steps.

In the Response to Arguments section of the final Office Action, at page 5, the Examiner asserts that Cornwall teaches a screw or fixation device going through a first vertebrae and into a second one, and that to perform this procedure, access to the spinal area would have been required, regardless of triangulation, and that Cornwall would ultimately fix

two vertebrae relative to one another. While Applicants agree that ultimately, Cornwall does fix two vertebrae relative to one another, Cornwall does not appear to teach the specific method steps recited in the claims. Applicants submit that a method claim requires a specific set of steps to be performed, and that a reference apparently teaching a similar outcome achieved through different steps cannot be seen to teach or suggest the specific claimed steps. Cornwall specifically teaches the most preferred method involving, "the placement of facet screws 30A and 30B is carried out using the same guideframe as was used to position the bone allografts." See column 7, lines 13-15. Cornwall also teaches using other guideframes and systems, all of which appear to involve a frame to which a narrow cannula is fixed for precise angled insertion. See column 7, lines 15-37 and FIG. 4.

The Examiner appears to be asserting that one of ordinary skill in the art would disregard the specific teachings of Cornwall for inserting screws at angled orientations using the narrow cannula to achieve the advantages provided by triangular support. Cornwall appears to teach specific advantages achieved by the triangular positioning of the screws and bone implants, using the recited narrow cannula. See column 1, line 66 through column 2, line 67. Further, Cornwall teaches their method of using facet screws and bone allografts to provide advantages over prior methods involving pedicle screws. See column 3, lines 32-40.

The example methods and systems disclosed in Davison directed at using an expandable elongate body for inserting separate fasteners into separate vertebrae and then using a fixation element to connect the fasteners appear to be quite different and involve different method steps and equipment than the method of Cornwall. In particular, Cornwall teaches, "the present narrow bone allografts are more easily inserted into the patient through a (narrower) cannulated passageway." See column 2, lines 47-49. Cornwall then teaches, "[m]ost preferably, the placement of facet screws 30A and 30B is carried out using the same guideframe as was used to position the bone allografts," and "cannula 72 is angled to facilitate the positioning of one of facet screws 30 therethrough in a transfacet approach." See column 7, lines 13-15 and 26-28 and FIGS. 3-4. Cornwall thus appears to teach a preferred method and system involving inserting 2 facet screws, where each screw is inserted through a separate narrow cannula at a specific angle through two vertebra.

As discussed in the response filed February 20, 2007, at page 10, third paragraph, it would appear that if an enlarged/expandable elongate body, as discussed in Davidson, were used in the method disclosed in Cornwall, it would defeat the purpose of Cornwall's specifically oriented guideframes that orient narrow cannulae to deliver narrow implants to specific locations at specific orientations. In other words, Cornwall thus appears to teach away from replacing their narrow cannula in the facet screw placement procedure with the enlarged/expandable elongate body of Davidson. In the Advisory Action the Examiner argued that Cornwall also teaches that separate components may be installed sequentially through a cannula. However, this insertion taught by Cornwall is through the specific narrow cannula described as providing the advantages discussed above.

Further, there does not appear to be any motivation or suggestion for one of ordinary skill in the art to attempt to substitute the device of Davison for the narrow cannulas of Cornwall. Each of Cornwall and Davison appear to teach different methods and apparatus for fixing two vertebrae. The Examiner has not provided any reasoned statements or specific motivation from a reference as to why one of ordinary skill in the art would have been motivated to modify the method of Cornwall by using the device of Davison. Additionally, as discussed above, such a modification would appear to frustrate the purpose of Cornwall. The Examiner has thus not met the burden of establishing a *prima facie* case of obviousness.

Applicants also respectfully point out that dependent claim 10 recites the added step of delivering a second fastener through the same access device used to deliver the first fastener, where the second fastener is advanced through the first vertebra and into the second vertebra. Independent claim 23 recites delivering first and second fastener through a single access device to first and second surgical locations, respectively. The Examiner has not addressed these claims. Cornwall appears to teach advancing first and second screws into first and second vertebrae through separate cannulas at specific different angles. See column 7, lines 9-28. Davison appears to teach inserting a single screw in each of two or more vertebra and then connecting the screws using a fixation member. Neither Davison nor Cornwall appear to teach or suggest each and every element of claims 10 and 23. Thus, even if one were to combine Davison and Cornwall, one would not arrive at the methods as claimed. As discussed above, MPEP 2143.03 states that in order to establish *prima facie* obviousness, all

of the claim limitations must be taught or suggested by the prior art. For at least the reasons set forth above, all of the claim limitations are not taught or suggested by Davison and Cornwall et al. The rejection is thus in error.

Claims 5 and 13 were rejected under 35 U.S.C. §103(a) as being unpatentable over the combination of Cornwall et al. (U.S. Patent No. 6,485,518) and Davison (U.S. Patent No. 6,530,926) as applied to claims 1 and 8, respectively above, and further in view of Neubardt (U.S. Patent No. 5,196,015). This rejection is respectfully traversed. As discussed above, there is no motivation for one of ordinary skill in the art to combine Davison and Cornwall, and even if such a combination were made, the elements of independent claim 1, from which claims 5 and 13 depend, are not taught or suggested. Neubardt does not appear to provide what Davison and Cornwall lack. Neubardt does not appear to provide any motivation or suggestion for modifying Davison and/or Cornwall to achieve the method steps recited in independent claim 1, or dependent claims 5 and 13. This rejection is thus in error.

Claims 19-20 and 21-22 were rejected under 35 U.S.C. §103(a) as being unpatentable over the combination of Cornwall et al. (U.S. Patent No. 6,485,518) and Davison (U.S. Patent No. 6,530,926). This rejection is respectfully traversed. For at least the reasons set forth above, Cornwall et al. and Davison do not appear to teach or suggest the elements of independent claims 1 and 14, from which claims 19-20, and 21-22 depend, respectively. There is no motivation for one of ordinary skill in the art to further modify Cornwall et al. and/or Davison to achieve the specific method steps recited in claims 19-22. Reconsideration and withdrawal of the rejections are respectfully requested.

CONCLUSION

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that the claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.


Respectfully submitted,

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By their attorney,

Date: _____

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